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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,520	02/14/2001	Geraldine Lerebour	2365-28	7537

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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

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8

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/782,520	LEREBOUR ET AL.
	Examiner Lauren Q Wells	Art Unit 1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_ .
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 13-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 13-32 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_ .
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                     | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-20 and 25-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the reduction of the adhesion of microorganisms to the skin, does not reasonably provide enablement for the prevention of the adhesion of microorganisms to the skin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The disclosure of the present invention is directed to a method of preventing or reducing the adhesion of microorganisms to the skin as set forth in independent claims 13 and 25. A skilled practitioner in the art using the teachings of Harbeck (2001/0001666) would be motivated to use fatty substances free of carbohydrate units to reduce or eliminate the adhesion of

microorganisms to the skin (fungicides). However, preventing the adhesion of microorganisms to the skin is inconsistent with what is known in the art since (1) reduction of the adhesion of microorganisms to the skin indicates that the adhesion is decreased, but not prevented; and (2) elimination of microorganisms to the skin indicates that symptoms of adhesion may occur. Furthermore, prevention of adhesion of microorganisms to the skin indicates that the subject never experiences any characteristics associated with the adhesion of microorganisms to the skin. Hence, the amount of guidance present in the specification, the absence of data indicating that the symptoms of the adhesion of microorganisms to the skin do not occur when a composition comprising at least one fatty substance free of carbohydrate units is topically applied, and the state of the prior art indicating that the treatment using a composition comprising at least one fatty substance free of carbohydrate units is possible, all indicate that treatment, not prevention of the adhesion of microorganisms to the skin is possible.

The amount of guidance necessary to perform Applicant's invention would result in undue experimentation because the skilled artisan would be forced to randomly test numerous conditions and amounts of fatty substances free of carbohydrate units in composition to determine what fatty substance composition prevents adhesion of microorganisms to the skin. Hence, the amount of guidance present in the specification fails to present the necessary instruction such that one can readily determine the appropriate composition of claims 13-20 and 25-32

**Note:** The Examiner reviewed Applicant's specification, but noted that the data does not indicate prevention of hair loss.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 21, 22, 23 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrase "so as to prevent or reduce" in claim 13 (line 2) and claim 25 (line 2) is vague and indefinite. Does this mean the method prevents or reduces adhesion of microorganisms? Does this mean the method could prevent or reduce the adhesion of microorganisms? Does this mean something else?

(ii) The term "modifying" in claims 13 and 25 (lines 5), the term "linked" in claim 21 (line 1), and the term "bad body odours" in claim 22 (line 4) are relative terms which render the claims indefinite. The terms "modifying", "linked", and "bad body odours" are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(iii) Claim 23 is vague and indefinite, as it is not clear how one fatty substance free of carbohydrate units can be admixed to itself. In order to admix, is there not a requirement for two or more ingredients?

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(j) of such treaty in the English language; (2) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by McCuaig (5,662,937).

McCuaig teaches a long life deodorant composition for foot odor. Disclosed is a composition comprising 0.67% calendula oil, which meets claim 22. See Col. 2, line 20-Col. 6, line 55.

Claim 22 is rejected under 35 U.S.C. 102(a) or (e2) as being anticipated by Averill et al. (5,882,666).

Averill et al. teach skin care compositions for the cleansing of skin. Disclosed is a composition comprising 5% jojoba oil and 2% isopropyl palmitate, which meets claim 22. See Col. 2, line 14-Col. 4, line 62.

Claims 13-17, 20-22, 25-29 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright (5,547,677).

Wright teaches antimicrobial oil-in-water emulsions. Disclosed is a composition comprising an oil, wherein the oil is selected from the group consisting of soybean oil, sesame oil, olive oil, canola oil, sunflower oil, and avocado oil, which meets claims 13-17, 20-22, 25-29 and 32. See Col. 2, line 10-Col. 6, line 67; Col. 11, line 58-Col. 14, line 19.

Claims 13-32 are rejected under 35 U.S.C. 102(e1) as being anticipated by Harbeck (2001/0001666).

Harbeck teaches cream compositions for skin management. The compositions are disclosed for treatment of acne and fungus. Disclosed are compositions comprising sweet almond oil, apricot kernel oil, jojoba oil, and others, which meets claims 13-32. See entire document.

Claims 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 05186328. '328 teaches nonaqueous skin washing and wiping agents having excellent sebum eliminating ability. The compositions are disclosed as comprising one or more oils selected from vegetable oils, such as olive oil or almond oil. The composition is specifically disclosed for use against acne vulgaris, which meets claims 22, 23, 24. See entire abstract.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright (5,547,677) in view of Harbeck.

Wright fails to teach the preferred percent weights of the active ingredients (see above disclosure).

Harbeck is disclosed as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have to have modified the composition of Wright using the teachings of Harbeck and obtain a composition comprising 5-25% of the active ingredient because a) Harbeck and Wright both teach antimicrobial compositions for topical application to the skin comprising vegetable oils and fatty acid esters; b) Harbeck teaches the vegetable oils as comprising a range of percent weights of the composition.

***Notes/Comments***

The Examiner respectfully suggests that Applicant use consistent and preferred Markush terminology throughout claims 13-32. See MPEP 2173.05(h) for examples of proper conventional or alternative Markush-type language (e.g., ". . . selected from the group consisting of . . . and . . .").

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
August 27, 2001



DAMERON L. JONES  
PRIMARY EXAMINER